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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,531	11/10/2003	Kun Ping Lu	2312/2002	8129

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,531	LU ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-69 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESTRICTION

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented claims 3-6, and 14-69 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed methods require the use and detection of distinct target molecules. A reference against one target molecule (i.e., an agonist) would not be a reference against the other target molecule (i.e., an agent that increases expression). Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-6, 47, 50 and 51, drawn to PinX1 nucleic acids , classified in Class 536, subclass 23.5.

II. I. Claims 2, 3-6, 47, 50 and 51, drawn to PinX1-L1 nucleic acids , classified in Class 536, subclass 23.5.

III. Claim 7, 48 and 51, drawn to PinX1 polypeptides, classified in Class 530, subclass 350.

IV. Claim 8, 48 and 51, drawn to PinX1-L1 polypeptides, classified in Class 530, subclass 350.

V. Claims 9-13, 49 and 51, drawn to antibodies to PinX1 polypeptides, classified in Class 530, subclass 387.1.

VI. Claims 14-20, 25 and 26, drawn to methods for diagnosing cancer by assaying for PinX1 nucleic acids, classified in Class 435, subclass 6.

VII. Claims 14-20, 25 and 26, drawn to methods for diagnosing cancer by assaying for PinX1-L1 nucleic acids, classified in Class 435, subclass 6.

VIII. Claims 21-26 , drawn to a method for diagnosing cancer by detecting a PinX1 protein, classified in Class 435, subclass 7.2.

IX. Claims 21-26, drawn to a method for diagnosing cancer by detecting a PinX1-L1 protein, classified in Class 435, subclass 7.2.

X. Claims 27, 29-32, and 34-37, drawn to methods for reducing telomere function using a PINX1 nucleic acid, classified in Class 514, subclass 44.

XI. Claims 27, 29-32, and 34-37, drawn to methods for reducing telomere function using a PINX1-L1 nucleic acid, classified in Class 514, subclass 44.

XII. Claims 28, 29-31, and 33-37 drawn to methods for reducing telomere function using a PinX1 protein, classified in Class 514, subclass 12.

XIII. Claims 28, 29-31, and 33-37 drawn to methods for reducing telomere function using a PinX1-L1 protein, classified in Class 514, subclass 12.

XIV. Claims 38, 40-43, 45-46, drawn to methods for increasing telomere function using antisense PINX1 nucleic acid, classified in Class 514, subclass 44.

XV. Claims 38, 40-43, 45-46, drawn to methods for increasing telomere function using antisense PINX1-L1 nucleic acid, classified in Class 514, subclass 44.

XVI. Claims 39-42, and 44-46, drawn to methods for increasing telomere function using an antibody PinX1 protein, classified in Class 424, subclass 155.1.

XVII. Claims 39-42, and 44-46, drawn to methods for increasing telomere function using an antibody to PinX1-L1 protein, classified in Class 424, subclass 155.1.

XVIII. Claims 52, 53 and 56-58, drawn to methods for identifying agents that modulate binding between PinX1 and Pin 2, classified in Class 435, subclass 7.2.

XIX. Claims 52, 53 and 56-58, drawn to methods for identifying agents that modulate binding between PinX1-L1 and Pin 2, classified in Class 435, subclass 7.2.

XX. Claims 54, 55 and 56-58, drawn to methods for identifying agents that modulate binding between PinX1 and telomerase, classified in Class 435, subclass 7.2.

XXI. Claims 54, 55 and 56-58, drawn to methods for identifying agents that modulate binding between PinX1-L1 and telomerase, classified in Class 435, subclass 7.2.

XXII. Claims 59-64, drawn to methods for identifying agents that modulate expression of PinX1, classified in Class 435, subclass 6.

XXIII. Claims 59-64, drawn to methods for identifying agents that modulate expression of PinX1-L1, classified in Class 435, subclass 6.

XXIV. Claim 65, drawn to methods for identifying agents that bind to a Pin2 polypeptide comprising SEQ ID NO: 8, classified in Class 435, subclass 7.2.

XXV. Claims 66, 68 and 69, drawn to methods of treatment using an agent that enhances binding between PinX1 and Pin2, classified in Class 514, subclass 1. Further classification cannot be determined without additional information regarding the structure of the agent.

XXVI. Claims 66, 68 and 69, drawn to methods of treatment using an agent that enhances binding between PinX1-L1 and Pin2, classified in Class 514, subclass 1. Further classification cannot be determined without additional information regarding the structure of the agent.

XXVII. Claims 67, 68 and 69, drawn to methods of treatment using an agent that increases expression of PinX1, classified in Class 514, subclass 1. Further classification cannot be determined without additional information regarding the structure of the agent.

XXVIII. Claims 67, 68 and 69, drawn to methods of treatment using an agent that increases expression of PinX1-L1 classified in Class 514, subclass 1. Further classification cannot be determined without additional information regarding the structure of the agent.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are drawn to patentably distinct nucleic acid sequences. Invention I is drawn to PinX1 nucleic acids, whereas invention II is drawn to PinX1-L1 nucleic acids. Each nucleic acid consists of a different nucleotide sequence, has a different melting temperature, a different specificity of hybridization and encodes for a protein having a different biological function. A search for the sequence of SEQ ID NO: 1 would not be co-extensive with a search for the sequence of SEQ ID NO: 5. Further, a finding that the sequence of SEQ ID NO: 1, is novel and unobvious over the prior art would not necessarily extend to a finding that the sequence of SEQ ID NO: 5 is also novel and unobvious over the prior art. Similarly, a finding that the sequence of SEQ ID

NO: 1 is anticipated or obvious over the prior art would not necessarily extend to a finding that the sequence of SEQ ID NO: 5 is also anticipated or obvious over the prior art. Given the differences in structure and function, the nucleic acids of invention I and II are patentably distinct from one another.

Inventions I and III, I and IV, II and III and II and IV are patentably distinct in structure and physicochemical properties. Inventions I and II are drawn to nucleic acids whereas inventions III and IV are drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins do not require the particular products of the nucleic acids of inventions I and II since the proteins can be isolated from natural sources or chemically synthesized.

Inventions I and V and II and V are patentably distinct in structure and physicochemical properties. Inventions I and II are drawn to nucleic acids whereas invention V is drawn to antibodies. The nucleic acids and antibodies differ in their structure, function and effect. While the nucleic acids of invention I and II consist of nucleotides, the antibodies of invention V encompass 2 heavy chains and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 CDRs that function to bind an epitope. The nucleic acids and antibodies also have different functional properties and can be utilized in different

methodologies, such that nucleic acids may be used in hybridization methods, whereas antibodies may be used in protein binding methods. Synthesis of the antibodies of inventions V does not require the particular products of the nucleic acids of inventions I and II since the antibodies can be isolated from natural sources or chemically synthesized.

Inventions I and VI, I and X, I and XIV, I and XXII, I and XXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions II and VII, II and XI, II and XV, II and XXIII, II and XXVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention II can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions I and VII, VIII, IX, XI, XII, XIII, XV-XXI, XXIII-XXVI and XXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions,

or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the nucleic acids of inventions I are not required to practice the methods of inventions VII, VIII, IX, XI, XII, XIII, XV-XXI, XXIII-XXVI and XXVIII.

Inventions II and VI, IX, X, XII, XIII, XIV, XVI-XXII, and XXIV-XXVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the nucleic acids of inventions II are not required to practice the methods of inventions VI, IX, X, XII, XIII, XIV, XVI-XXII, and XXIV-XXVII.

Inventions III and IV are drawn to patentably distinct proteins. Invention III is drawn to PinX1 proteins, whereas invention II is drawn to PinX1-L1 proteins. Each protein consists of a different amino acid sequence, has a different isoelectric point, a different specificity of binding and a different biological function. A search for the sequence of SEQ ID NO: 3 would not be co-extensive with a search for the sequence of SEQ ID NO: 6. Further, a finding that the sequence of SEQ ID NO: 3, is novel and unobvious over the prior art would not necessarily extend to a finding that the sequence of SEQ ID NO: 6 is also novel and unobvious over the prior art. Similarly, a finding that the sequence of SEQ ID NO: 3 is anticipated or obvious over the prior art would not necessarily extend to a finding that the sequence of SEQ ID NO: 6 is also anticipated or obvious over the prior art. Given the differences in structure and function, the nucleic acids of invention I and II are patentably distinct from one another.

Inventions III and V and IV and V are patentably distinct in structure and physicochemical properties. Invention III and IV are drawn to proteins whereas invention V is drawn to antibodies. The proteins and antibodies differ in their primary amino acid sequence and in the secondary and tertiary structures. While the protein of invention II is a single chain molecule, the antibody of invention III encompasses 2 heavy chains and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 CDRs that function to bind an epitope. The proteins and antibodies also have different functional properties and can be utilized in different methodologies. Synthesis of the antibodies of inventions V does not require the particular products of the proteins of inventions III and IV since the antibodies can be isolated from natural sources or chemically synthesized. Further, antibodies which bind to an epitope of the protein of group II may be known even if the protein is novel.

Inventions III and VI, VII, IX, X, XI, XIII, XIV, XV, XVII, XIX, XXI, XXII, XXIII, XXIV, XXVI, XXVII, and XXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the specific proteins of inventions III are not required to practice the method set forth in inventions VII, VIII, IX, XI, XII, XIV, XV, XVII, XIX, XXI, XXI, XXIII, XXVI, XXVII, and XXVIII.

Inventions IV and VI, VII, VIII, X, XI, XII, XIV, XV, XVI, XVIII, XX, XXII, XXIV, XXV, XXVII, and XXVIII are unrelated. Inventions are unrelated if it can be shown that

they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the specific proteins of inventions IV are not required to practice the method set forth in inventions VI, VII, VIII, IX, X, XI, XII, XIV, XV, XVI, XVIII, XX, XXII, XXIV, XXV, XXVII, and XXVIII.

Inventions III and VII, VIII, XII, XVI, XVIII, XX, XXV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the proteins of invention III can be used in a materially different process, such as for synthesizing antibodies.

Inventions IV and X, XIII, XVII, XIX, XXI, XXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the proteins of invention IV can be used in a materially different process, such as for synthesizing antibodies.

Inventions V and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. ∋ 806.05(h)). In the instant case, the antibodies of invention V can be used in a materially different process, such as for isolating proteins.

Inventions V and VI-XV and XVII-XXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the antibodies of invention V are not required to practice the methods of inventions VI-XV and XVII-XXVIII.

Inventions VI-XXVIII are drawn to patentably distinct methods. Each of the claimed methods requires the use of different reagents, involves performing different process steps and has a different outcome or objective. Accordingly, the methods of inventions VI-XXVIII are patentably distinct from one another.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-XXVIII require different searches that are not co-extensive. For instance, a literature and sequence search for the nucleic acids of invention I is not co-extensive with a literature and sequence search for the proteins of invention III or the antibodies of invention V or a search for the methods of inventions VI-XXVIII. Additionally, a search for each of the methods of inventions VI-XXVIII is not co-extensive with one another. For instance, a keyword / literature search for methods of detecting a PinX1 protein as diagnostic of cancer (invention VIII) would not be co-

extensive with a keyword / literature search for methods for treating a patient with cancer by administering a PinX1 nucleic acid (invention X). Further, a finding that the method of invention VI is anticipated or obvious over the prior art would not necessarily extend to a finding that the method of inventions VII-XXVIII were also anticipated or obvious over the prior art. Similarly, a finding that the method of invention VI is novel and unobvious over the prior art would not necessarily extend to a finding that the methods of invention VII-XXVIII are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. ə 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
April 17, 2006

CARLA J. MYERS
PRIMARY EXAMINER